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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,872	06/29/1998	SYDNEY M PUGH	3477/116	6664

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/029,872

Applicant(s)

PUGH ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 10, 12-15, 19-35 and 37-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 12-15, 19-35 and 37-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The indicated allowability of claims 10, 20, and 37 is withdrawn in view of the newly discovered reference(s) to Ruys (article entitled "Silicone-Doped Hydroxyapatite"). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15 and 21-23 are rejected under 35 U.S.C. 102(a) or 102(b)* as being anticipated by Davies (WO 94/26872), or alternatively, under 35 U.S.C. 103(a) by Davies (WO 94/26872) alone. Davies discloses a sintered hydroxyapatite and tricalcium phosphate film on quartz (see pages 26-28). This procedure is identical to the present specification's manner of stabilizing hydroxyapatite due to the silica of quartz permeating into the sol during sintering; see Procedure 3 on page 30 of the

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present specification and note that only the bulk ceramic pieces need to be doped with a stabilizer because the quartz substrate inherently dopes the sol-gel.

The Examiner posits that the stabilization of hydroxyapatite is not mentioned by Davies, nonetheless, this property is inherently present because it is made the same way as in the present specification; see also pages 6, 7, and 15 of Davies.

Moreover, the distribution of the silicon entities is considered to be **"primarily"** uniform, as claimed, because this term allows for much variation. In particular, the language does not preclude the presence of a gradient as long as it is not too pronounced.

In addition, since the Davies layer is rather thin, it would have silicon diffused throughout.

The Examiner asserts that the sol gel can be considered uniformly doped, but not uniformly distributed and **"primarily"** uniformly stabilized tricalcium phosphate. This is due to the fact that uniform doping encompasses doping on a surface of a material as well as distributing the doping material throughout.

*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996. Alternatively, if the earlier date for the claims has support, the Davies constitutes a 35 USC 102(a) reference. Moreover, it is posited that claim 38 has the August 30, 1996 effective filing date because it does not preclude other entities and can encompass a plurality of later added stabilization entities.

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Alternatively, one could view the Davies et al disclosure as not fully meeting the claim language because it does not explicitly teach uniform distribution. However, the Examiner posits that the substantially uniform distribution of stabilizing entities is at least obviated by Davies because of the diffusion of the entities into the surface.

Claims 1-3, 5, 6, 12-15, 21, 23, 24, and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kijima et al (US 4,983,182) wherein zirconia is used to stabilize hydroxyapatite to the extent required by the present claims; see the whole document. In particular, the coating of zirconia and HAP forms a stabilized coating or phase of alpha TCP, and thus, the claim language is fully met.

Claims 1-3, 5, 6, 12-15, 19, 21-25, 31, 32, 34, 38-41, 43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruys (article entitled "Silicone-Doped Hydroxyapatite"). Ruys anticipates the claim language wherein the morphology and solubility characteristics claimed are inherently met by Ruys because the same material is used as claimed and disclosed and it is made by the same process as claimed and disclosed; see the whole document, especially pages 71-73.

Claims 10, 20, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) alone.

With regard to claims 10 and 20, Ruys uses tetraethyl orthosilicate instead of tetrapropyl orthosilicate as claimed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use tetrapropyl orthosilicate in place of tetraethyl orthosilicate because Applicant has not disclosed that tetrapropyl orthosilicate provides an

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advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with tetraethyl orthophosphate because it is from the same class of compounds and is quite chemically similar thereto. Therefore, it would have been an obvious matter of design choice to modify Ruys to obtain the invention as specified in claims 10 or 20.

With regard to claim 26, Ruys fails to disclose the particle size as claimed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use the claimed particle size because Applicant has not disclosed that the claimed particle size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the claimed particle size because it is in the size range of a powder form and many chemical agents and drugs are provided in such a form. Therefore, it would have been an obvious matter of design choice to modify Ruys to obtain the invention as specified in claim 26.

Claims 27-30, 35, 37, 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Davies (WO 94/26872). Ruys meets the claim language except for the presence of bone cells or their excreted materials. However, Davies teaches that it was known to prepare implants by culturing bone cells on the material or implant in order to test it; see the whole document, especially the abstract.

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With regard to claims 27-29, the Examiner posits that the claimed matrix would inherently be formed in the Davies modified Ruys device due to the same device being exposed to the same cells for a sufficient time for such matrix to form.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Kijima et al (US 4,983,182). Ruys discloses the composition as claimed but fails to teach using it to form a coating on an implant as claimed. However, Kijima teaches that it was known to do so in order to render implants bioactive. Hence, it is the Examiner's position that it would have been obvious to coat an implant with the Ruys material for the same reasons that Kijima does the same and in order to reduce the cost of making a large implant.

Response to Arguments

Applicant's arguments filed March 27, 2002 have been fully considered but they are not persuasive. Many of the rejections have been withdrawn and replaced with a new ground of rejection utilizing Ruys.

With regard to the Davies traversal, Applicants are directed to the new rejection, which addresses the issues raised. In particular, the doping and "primarily" uniform language is viewed as being met by Davies because such language encompasses that set forth in Davies.

With regard to the Kijima traversal that Kijima is not a bioactive material, the Examiner posits that Kijima's disclosure of biological activity is sufficient to meet the claim language. The type of bioactivity would have to be specified in order to distinguish it from Kijima. Furthermore, since the same material is both claimed herein

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and disclosed by Kijima, it would inherently function the same manner *in vivo*. For this reason, the arguments are considered unpersuasive.

Applicants argue that Kijima uses the stabilized zirconia for enhanced mechanical stability. In response, the Examiner notes that the coating is what is applied against the present claims and not the implant body. Furthermore, the intended function of the material is not determinative of patentability in product claims. As long as all the structural limitations are met, the claims are considered to be anticipated under 35 USC 102.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilit whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a long horizontal flourish extending to the right.

Paul Prebilic
Primary Examiner
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